

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION****OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS****SOP Number: 16A****SOP Title: ALLEGATIONS OF NON-COMPLIANCE WITH REQUIREMENTS OF
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SOP 16A – ALLEGATIONS OF NON-COMPLIANCE WITH REQUIREMENTS OF THE NIH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

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SOP 16A – ALLEGATIONS OF NON-COMPLIANCE WITH REQUIREMENTS OF THE NIH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

16A.1 PURPOSE

This policy provides definitions, procedures, sample corrective actions, and reporting requirements related to possible non-compliance with requirements of the NIH Human Research Protection Program (HRPP) policies, and applicable regulatory requirements for the protection of human subjects.

16A.2 POLICY

NIH strongly encourages persons to report, through proper channels, all observed or apparent incidents of non-compliance. These incidents may concern active or closed protocols or non-protocol issues related to HRPP policies.

It is the policy of the NIH Human Research Protection Program (HRPP) to investigate allegations of non-compliance with NIH HRPP policy and other requirements in a methodical and fair manner and, if necessary, to take corrective action commensurate with the nature and degree of non-compliance. The type of allegation determines the process, as set forth in this Standard Operating Procedure (SOP). When the allegation regards an active protocol, NIH Institutional Review Boards (IRBs) are the primary entities responsible for conducting the investigation of non-compliance. When an allegation regards non-compliance by an NIH IRB, or NIH official, or involves other aspects of the HRPP not related to an active protocol, the Deputy Director for Intramural Research (DDIR) determines who will conduct the investigation of non-compliance. The Office of Human Subjects Research Protections (OHSRP) may also participate in these activities, depending on the nature of the issue.

This SOP does not explain the separate process by which Principal investigators (PIs) are required to self-report certain instances of non-compliance related to protocols and the IRB review of such reports. (For more information, see 16A.7.2 and the process detailed in SOP 16 – Reporting Requirements for Unanticipated Problems, Adverse Events, and Protocol Deviations.)

16A.3 DEFINITIONS

Active protocol: Approved NIH protocols that are open for patient accrual and/or follow-up, or for which data analysis and/or specimen storage/research are ongoing. Protocols that are closed or terminated are not active protocols.

Allegation of non-compliance (also “allegation”): A disclosure of possible non-compliance through any means of communication (e.g., by written or oral statement) to an NIH official. This may include concerns from research participants, researchers, staff, IRB members, reports from audits, and discoveries made during review of other human subjects issues, such as protocol deviations. It does not include self-reporting by the PI to the IRB, using a problem report form.

Complainant: A person who makes an allegation of non-compliance.

Investigation of non-compliance: The assessment, information-gathering and formal determination of whether non-compliance occurred. The conclusion of an investigation may result in actions by an IRB and/or Institute/Center (IC) or NIH officials.

Non-compliance: The failure to comply with applicable NIH HRPP policies, IRB requirements, or regulatory requirements for the protection of human research subjects. This may include, but is not limited to, the following:

- A. Failure to obtain IRB approval for research involving human subjects.
- B. Inadequate or non-existent procedures for informed consent.
- C. Inadequate supervision of research involving experimental drugs, devices, or procedures.
- D. Failure to follow an IRB-approved protocol: protocol deviations are a form of non-compliance (See SOP 16 – Reporting Requirements for Unanticipated Problems, Adverse Events, and Protocol Deviations).
- E. Failure to obtain prospective IRB approval for changes to a protocol.
- F. Failure to report unanticipated problems and protocol deviations (see SOP 16 – Reporting Requirements for Unanticipated Problems, Adverse Events, and Protocol Deviations).
- G. Failure to obtain continuing IRB review and approval.

H. Failure to ensure appropriate training of study personnel.

Non-compliance may result from the action of the investigator, research personnel, or a participant, and may or may not impact the rights and welfare of research participants or others or the integrity of the study.

Non-compliance may be further characterized as:

A. **Serious non-compliance:** Non-compliance that:

1. Increases risks, or causes harm, to participants,
2. Decreases potential benefits to participants, or
3. Compromises the integrity of the NIH HRPP

B. **Continuing non-compliance:** Non-compliance that is recurring, regardless of whether it is serious or minor. An example may be a pattern of non-compliance that suggests a likelihood that, absent an intervention, non-compliance will continue. Continuing non-compliance could also include a failure to respond to IRB requests to resolve previous allegations of non-compliance.

C. **Minor (non-serious) non-compliance:** Non-compliance that is neither serious nor continuing.

Preliminary review of non-compliance: The preliminary review of an allegation of non-compliance involves a set of questions that determine the appropriate process for resolution of the allegations.

Respondent: The PI or the person(s) or the entity, if any, against whom an allegation of non-compliance is made. The respondent is expected to comply with requests pursuant to this SOP.

16A.4 RAISING AND DOCUMENTING ALLEGATIONS OF NON-COMPLIANCE

16A.4.1 WHO MAY RAISE ALLEGATIONS OF NON-COMPLIANCE

- A. Researchers, staff and employees may discover possible non-compliance through continuing reviews, audits, reports of unanticipated problems and

protocol deviations. The PI should report unanticipated problems and protocol deviations to the Clinical Director and IRB using the NIH Problem Report Form attached to SOP 16 – Reporting Requirements for Unanticipated Problems, Adverse Events, and Protocol Deviations. Protocol deviations and some unanticipated problems represent non-compliance, and this should be indicated on the form.

- B. Any individual or organization may raise an allegation of non-compliance. Such allegations would be considered as described below.
- C. Allegations of non-compliance made in good faith will not reflect negatively on the reporting individual, nor lead to reprisal against that individual.
- D. Possible non-compliance may be discovered by an IRB, OHSRP, the DDIR or other IC official, as part of their oversight responsibilities and not as a result of an allegation from another individual or entity. These situations will be handled by the HRPP by the process set forth in this SOP (i.e., preliminary review as needed and investigation of non-compliance).

16A.4.2 **TIMING, METHOD AND CONTENT FOR REPORTING ALLEGATIONS OF NON-COMPLIANCE**

- A. Allegations of non-compliance should be reported as soon as possible.
- B. Allegations of non-compliance may be submitted verbally or in writing (via mail or email) to the appropriate IRB, OHSRP, the DDIR or other IC official.

Allegations of non-compliance may be made anonymously, e.g., by leaving a telephone message or submitting an unsigned document. Such allegations will be pursued only to the extent that sufficient information is available to perform a review of non-compliance.

The identity of the individual making an allegation of non-compliance will be kept confidential to the extent possible. Disclosure will be limited to those who need to know, consistent with a thorough, competent, objective and fair proceeding, and except as may otherwise be prescribed by applicable law.

Allegations of non-compliance should include a description of the possible non-compliance, including the protocol title, number, date, time, personnel involved and complainant's name and contact information, if available.

16A.4.3 DOCUMENTATION OF ALLEGATIONS OF NON-COMPLIANCE

Allegations of non-compliance, whether written or verbal (including anonymous allegations), will be documented and kept on file in the IRB administrative office or OHSRP, as applicable. The following information will be documented:

- A. Title, number and PI of the protocol.
- B. A description of the alleged non-compliance including the date, time, personnel involved, and
- C. The name and contact information of the person reporting the non-compliance, unless the allegation is anonymous. The identity of the individual reporting the allegation will be kept confidential to the extent possible but complete confidentiality is not anticipated, as information will be shared on a need to know basis and for purposes of investigating and resolving the alleged non-compliance.

16A.4.4 NOTIFICATION OF ALLEGATIONS

When an allegation involving serious or continuing non-compliance is received, the NIH official or office receiving the allegation (e.g., IRB, OHSRP, the DDIR or other IC official) will notify the appropriate IRB and OHSRP, if not already informed, as soon as possible (and no later than 2 working days after receipt). When the allegation involves the IRB (see 16A.9, below), the NIH official or office receiving the allegation will inform the DDIR and OHSRP, if not already informed.

The IRB, OHSRP, or DDIR will notify the respondent, in writing, of the allegations and the process of investigation of non-compliance within 5 working days of performing a preliminary review of non-compliance, if the preliminary review finds that an investigation of non-compliance is needed.

16A.5 RESPONSE TO POSSIBLE SERIOUS AND/OR CONTINUING NON-COMPLIANCE

At any point in this process, if any individual or entity considers that serious and/or continuing non-compliance has occurred or is likely to occur, the individual or entity should notify the IRB and, if authorized, s/he may decide that research should be placed on an administrative hold. The IRB has the authority to suspend the protocol (see SOP 11 – Suspensions and Terminations of IRB-approved Research and Administrative Holds).

16A.6 INDIVIDUALS OR GROUPS THAT CONDUCT AN INVESTIGATION OF NON-COMPLIANCE

A. Investigation of possible non-compliance related to active protocols

NIH IRBs have the primary responsibility for conducting an investigation of non-compliance that is related to active protocols, including those in data analysis only. In most circumstances, the IRB is responsible for assessing the possible non-compliance and, as part of the information gathering stage, gathering information (as necessary) and otherwise engaging in actions necessary to investigate the possible noncompliance. The IRB may request assistance from OHSRP. In some cases, an *ad hoc* Special Committee may assist in the assessment and information gathering. In cases where an investigation of non-compliance is related to an active protocol, including those involving a Special Committee, the IRB is the only entity that makes determinations about non-compliance.

B. Investigation of possible non-compliance not related to an active protocol

The DDIR determines who will conduct the investigation of non-compliance not related to an active protocol. The DDIR may appoint a Special Committee for this purpose. The DDIR may consult with other NIH officials in making this decision, including IRB chairs and the OHSRP Director. The DDIR may decide that more than one group (e.g., OHSRP and an IRB, or a Special Committee and an IRB) should work together to investigate the non-compliance. Such allegations may include non-compliance with HRPP policies by an NIH IRB, NIH official or leader, or other NIH staff.

16A.6.1 APPOINTMENT OF A SPECIAL COMMITTEE BY THE DDIR

If in the judgment of the DDIR a Special Committee is needed, the DDIR will select the individuals to serve on the Special Committee and appoint a Chair. A Special

Committee may consist of a representative from OHSRP, the relevant IRB Chair or a designated representative from the IRB, and/or other NIH employees, depending on the nature of the issue.

A. Factors that may justify creation of a Special Committee:

1. Immediate action is required to protect human subjects.
2. The issue involves more than one IC or NIH IRB.
3. The issue involves an outside institution.
4. The allegation involves non-compliance by an IRB or NIH official
5. Outside entities, such as Congress or the Inspector General, are requesting information from NIH about the non-compliance.
6. The allegation is not related to active protocol(s) but involves non-compliance with HRPP policies

B. Responsibilities of a Special Committee:

1. The Special Committee will assess possible non-compliance and gather information according to an information-gathering plan established by OHSRP and/or the IRB Chair on a case by case basis. The Special Committee may, for example, perform internal or independent audits, document reviews, and/or interview the PI and other individuals who have knowledge of the issues.
2. The Special Committee will, as appropriate, prepare a report that includes the name of the respondent(s), a description of the possible non-compliance, a list of the evidence examined, and summary or source documents (if pertinent). This work will be completed as soon as possible, generally no later than forty-five (45) days from receipt of the allegation by the Special Committee. The Special Committee will provide this report to the appropriate NIH IRB, the respondent and the DDIR.
3. Records will be maintained of the Special Committee's activities.

16A.6.2 CONSULTANTS

If there are issues pertinent to other research review committees, e.g., NIH Biosafety Committee, NIH Radiation Safety Committee, relevant Animal Care and Use Committee, these entities will be contacted to determine if their involvement or consultation is appropriate. Additionally, the individuals or groups performing an investigation of non-compliance may seek advice from expert consultants as necessary (e.g., FDA expertise).

16A.7 PRELIMINARY REVIEW AND INVESTIGATION OF NON-COMPLIANCE REGARDING ACTIVE PROTOCOLS

16A.7.1 THE PROCESS FOR DECISION-MAKING WHEN AN NIH OFFICIAL (IRB, DDIR OR OHSRP) OBTAINS AN ALLEGATION OF NON-COMPLIANCE

A. Preliminary review of non-compliance

The first step is a preliminary review, by the IRB, DDIR or OHSRP, on a case-by-case basis. The review involves the following three questions:

1. Is the allegation credible?
2. Does the allegation fit within the scope of the IRB's purview? (OHSRP may advise if there are any questions about the purview of the IRB and/or scope of the NIH HRPP.)
3. Does the allegation involve possible serious or continuing non-compliance?

The preliminary review will take place within seven working days of receipt of the allegation by the appropriate NIH official.

If the answer is "yes" to all of the questions above, an investigation of non-compliance will occur as outlined below. The preliminary reviewing official should notify other officials so that the appropriate NIH IRB, OHSRP and the DDIR are all aware. The respondent should be notified per 16A.4.4.

If the answer to questions 1 or 2 is "no," the matter should be dismissed or referred to a more appropriate entity for consideration, e.g., allegations concerning scientific misconduct in the Intramural Program should be referred in accord with NIH Intramural Research Program Policies & Procedures for

Research Misconduct. If the answer to both questions 1 and 2 is “yes,” but the answer to 3 is “no,” the IRB should proceed with the matter as an issue involving non-compliance that is neither serious nor continuing (see SOP 16 – Reporting Requirements for Unanticipated Problems, Adverse Events, and Protocol Deviations).

B. Investigation of non-compliance:

Information-gathering stage: The purpose of the information-gathering stage is to **assess** the nature of the **possible non-compliance** and to collect relevant available evidence concerning **possible serious or continuing non-compliance**. **OHSRP and the IRB Chair, with DDIR input on a case-by-case basis, should agree on an information-gathering plan.** In some cases, depending on the information-gathering plan, this may involve the creation of a Special Committee. **Other times the information-gathering stage will be performed by the IRB (in whole or part), possibly with the assistance of its administrative staff.** At the conclusion of this stage, additional information may be summarized in an evaluation report **with summary or source documents (if pertinent).** This **evaluation report** does not make conclusions or result in a determination of non-compliance. **The evaluation report will be shared with the respondent (to the extent permitted by law).**

IRB formal determinations: A convened IRB meeting will be scheduled so that the respondent and IRB members have sufficient time (generally not more than 30 days) to assess the **possible non-compliance and information gathered about the possible non-compliance (including, but not limited to, the Special Committee’s report and the evaluation report, if any).** The IRB may need to schedule additional IRB meetings in addition to its regularly scheduled meeting(s) to address the **possible non-compliance** in a timely manner.

If the respondent wishes to provide written materials, the materials must be provided to the IRB at least three working days before the meeting. All reports, documents and written materials will be provided to the entire IRB; primary reviewers will not be used.

If the IRB adds allegations to those already communicated to the respondent, or obtains additional information than that which is provided in the Special Committee and/or evaluation report (if any), the respondent must be provided with a copy of these new allegations and/or **additional information (to the extent permitted by law)** and the respondent must be given an opportunity to respond.

At the convened meeting, the IRB will review all information provided and decide whether more information is needed. It will give the respondent an opportunity to respond to the allegations. The respondent may bring counsel (as a guest, not to represent the respondent) to the IRB meeting if the IRB is notified at least 24 hours in advance of the meeting. A confidentiality requirement may be imposed as appropriate, consistent with law or NIH policy (e.g., for discussion of Privacy Act-protected data.)

At the same or subsequent convened meeting (should additional information be needed), the IRB will make a determination of whether the evidence represents minor, serious and/or continuing non-compliance, and what, if any, additional IRB action is required. The IRB will vote and document its determinations and actions in the meeting minutes. The IRB will communicate its decisions to the respondent and other appropriate NIH officials, e.g. as described below.

16A.7.2 THE PROCESS FOR DECISION-MAKING WHEN AN IRB REVIEWS PROBLEM REPORTS FROM A PI REGARDING POSSIBLE NON-COMPLIANCE

A convened IRB reviews problem reports according to SOP 16 – Reporting Requirements for Unanticipated Problems, Adverse Events, and Protocol Deviations. The IRB may recommend further investigation of non-compliance as part of its determination and action plan. This may occur, for example, if the IRB recalls previous problem reports that, in conjunction with the current report, might represent continuing non-compliance. Such further investigation would proceed according to 16A.7.1.B above.

16A.7.3 IRB ACTIONS

After an IRB determination of non-compliance is made, possible actions include:

- A. Action on a finding of minor non-compliance: The IRB may allow the research to continue with no further action required or may require modifications that constitute a minor change in the research. If changes to the research protocol are required, the PI will submit an amendment to the IRB. Minor changes to previously approved research may be eligible for review under expedited review procedures consistent with the requirements of SOP 7A - Requirements for Expedited Review of Research by NIH IRBs.

- B. Action on a finding of serious and/or continuing non-compliance: The IRB will take prompt and appropriate action to assure the safety and welfare of human research subjects and the integrity of the research. These actions may include, but are not limited to, the following:
1. Require modifications in the protocol and/or consent document(s), or require consent monitoring.
 2. Require that subjects who are still participating in the research be notified of the non-compliance and/or re-consented.
 3. Require, if appropriate, that subjects whose participation has ended be notified of the non-compliance.
 4. Modify the continuing review schedule.
 5. Suspend the research (see SOP 11 – Suspensions and Terminations of IRB Approval and Administrative Holds).
 6. Terminate the research (see SOP 11 – Suspensions and Terminations of IRB Approval and Administrative Holds).
 7. Require monitoring of the research by a QI/QA team (see SOP 23 – Quality Management System for the NIH HRPP) and/or the IRB.
 8. Require educational measures for researchers/research staff.
 9. Any other remedial or corrective action the IRB deems appropriate.
- C. Non-HRPP issues: The investigation of possible non-compliance may uncover **issues** that are not under the HRPP purview of OHSRP or the IRB. For example, poor record keeping or inadequate supervision of clinical procedures not related to the human subjects research might not be a matter of HRPP compliance. The IRB/OHSRP may not make determinations about these issues, but may refer their concerns to other appropriate entities such as the IC or Clinical Center, to address appropriately, consistent with applicable law and NIH Policies.

16A.8 REQUEST FOR IRB RECONSIDERATION

Researchers may request reconsideration of an IRB determination of non-compliance for good cause. Examples of this circumstance include, but are not limited to, the following:

- A. New information exists that was not available during the investigation.
- B. Material failure by the OHSRP, the IRB or other investigative group to follow the non-compliance policy and procedures set forth in this SOP.
- C. The corrective action(s) is perceived to exceed the severity of the non-compliance.

16A.8.1 PROCESS FOR IRB RECONSIDERATION

An appeal for reconsideration of the decision of the IRB will be handled in accordance with SOP 7 – Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs), and SOP 11 – Suspensions and Terminations of IRB Approval and Administrative Holds, as applicable.

16A.8.2 ADDITIONAL INSTITUTIONAL ACTIONS

The DDIR may institute additional actions as needed to address HRPP and other institutional issues. The IC may institute actions related to areas in its purview, e.g. personnel matters.

16A.9 INVESTIGATION OF NON-COMPLIANCE THAT DOES NOT INVOLVE AN ACTIVE PROTOCOL

Allegations of non-compliance that do not involve an active protocol will undergo the following process.

16A.9.1 PRELIMINARY REVIEW OF NON-COMPLIANCE AND CREATION OF AN INFORMATION-GATHERING PLAN:

The DDIR or OHSRP, at the DDIR's discretion, will perform a preliminary review to determine whether the possible non-compliance is within the scope of this SOP, whether it has may have merit (e.g., there are supporting evidence, documents or statements), and whether it represents possible serious or continuing non-compliance with NIH HRPP policies.

The entity/official(s) tasked by the DDIR (e.g., IRB, Special Committee and OHSRP) will prepare an information-gathering plan to obtain additional information. This information-gathering plan may include, for example, audits or interviewing individuals who have knowledge of the events.

16A.9.2 INFORMATION-GATHERING STAGE:

The entity/official(s) conducting the investigation of non-compliance will assess the possible non-compliance, gather relevant evidence pursuant to the information-gathering plan, prepare an evaluation report that includes the name of the respondent(s), a description of the allegations, a list of the evidence examined, and summary of or copies of source documents (if pertinent). This work will be completed as soon as possible, generally no later than forty-five (45) days from receipt of the allegation by those conducting the investigation of non-compliance. This report will be provided to the DDIR and to the respondent(s). If the official(s) conducting the investigation of non-compliance add allegations to those provided to the respondent(s) or requests additional information, the respondent(s) must be provided with a copy of these new allegations and/or additional information (to the extent permitted by law) and given sufficient time to review and respond.

Those conducting the investigation of non-compliance will meet to review the allegations and evidence, decide whether additional evidence is needed, and give the respondent(s) an opportunity to respond to the allegations. The respondent(s) may bring counsel (as a guest, not to represent the respondent(s)) if 24 hours advance notice is provided. Other DHHS/NIH officials may be invited to attend the meeting.

16A.9.3 FORMAL DETERMINATION:

Those conducting the investigation of non-compliance will then make a determination of whether the evidence represents serious, minor or continuing non-compliance, or whether the allegation is unjustified and no action is required.

Those conducting the investigation of noncompliance will document its determination(s) in writing and make recommendations to the DDIR regarding possible corrective action. The DDIR will institute corrective actions as needed.

16A.10 IRB AND OHSRP REPORTING TO NIH OFFICIALS AND OTHER ENTITIES

- A. At any point during the proceeding, if a convened IRB or OHSRP determines that facts suggest serious and/or continuing non-compliance, the appropriate NIH officials will be notified (e.g., the DDIR, the appropriate Clinical Director, and/or other IC officials).
- B. Determinations of serious and/or continuing non-compliance will be reported to OHSRP.
- C. Reporting to OHRP and the FDA will be handled according to SOP 24 – OHSRP Reporting to the Office of Human Research Protections (OHRP) and The Food and Drug Administration (FDA) Regarding Unanticipated Problems, Serious or Continuing Non-Compliance, or Terminations or Suspensions. The IRB has no responsibility to initiate any public disclosure of the findings.
- D. If there is evidence of a possible violation of the NIH policy on misconduct in scientific research, the matter will be forwarded to the NIH Agency Intramural Research Integrity Officer (AIRIO) for further action.